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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,553	02/08/1999	DANIEL NORMAN GALBRAITH	CFV-005.01	8196

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EXAMINER	
SHUKLA, RAM R	

ART UNIT	PAPER NUMBER
1632	20

DATE MAILED: 03/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/171,553	Applicant(s) GALBRAITH ET AL.	
	Examiner Ram Shukla	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-65* is/are pending in the application.

4a) Of the above claim(s) *65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

DETAILED ACTION

1. Applicant's election of the invention of group I, claims 43-64 and SEQ ID NO 13 as the species in Paper No. 19 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claim 65 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 19.

3. Amendments to the specification have been entered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 43-47 and 49-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the revised interim guidelines on written description published December 21, 1999 in the Federal Register, Volume 64, Number 244, page 71427-71440 (also available at www.uspto.gov).

When the claims are analyzed in light of the specification, the instantly claimed polynucleotides encompass any polynucleotides that have at least 75% or 90% sequence identity to the sequence of SEQ ID NO 1, 2, 3, or 9. However, the specification discloses only SEQ ID No 1, 2, 3, and 9, out of which SEQ ID NO 1 and 2 are partial sequences of SEQ ID NO 3. SEQ ID NO 3 has three ORFs which

encode the polypeptides disclosed in SEQ ID NO 4, 5, and 6. SEQ ID NO 9 encodes the polypeptide of SEQ ID NO 10. In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, SEQ ID NO 1, 2, 3 and 9 are the only species whose complete structure is disclosed. The specification does not provide any disclosure as to what would have been the sequence structure of any other sequence encompassed the claimed genus of polynucleotides.

Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, no other identifying characteristics have been disclosed. It is noted that as instantly recited, claimed polynucleotides would encompass those derived from any species, however, it is noted that the specification does not provide any disclosure whether these sequences from other species would have had same characteristics or would have had additional characteristics or properties. While the claims are interpreted to include synthetic and naturally occurring variants of the polynucleotides, the specification does not provide the features essential for the operability of the polynucleotides encompassed by the claimed invention.

This limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of polynucleotides of SEQ ID NO 1, 2, 3, and 9, of which SEQ ID NO encodes the polypeptides disclosed in SEQ ID NO 4, 5, and 6, while SEQ ID NO 9 encodes the polypeptide of SEQ ID NO 10 at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

6. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (i) an isolated polynucleotide disclosed in SEQ ID NO 1, 2 and 3 wherein the polynucleotides of SEQ ID NO 2 and 3 have three open reading frames (ORFs) of 524 (SEQ ID NO 4), 1194 (SEQ ID NO 5), and 656

amino acids each (SEQ ID NO 6) (ii) an isolated polynucleotide disclosed in SEQ ID NO 9 which encodes the protein disclosed in SEQ ID NO 10, vector comprising the polynucleotides of (i) and (ii), and an isolated recombinant host cell comprising the polynucleotides of (i) and (ii), does not reasonably provide enablement for any other claimed embodiments. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make and use the claimed invention, if not, whether an artisan would have required undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue" (In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). Furthermore, USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of expertise.

In the instant case, the specification as filed has described three figures that contain sequence information of polynucleotides. SEQ ID NO 1 and 2 are partial sequences of SEQ ID NO 3. SEQ ID NO 3 has three ORFs which encode the polypeptides disclosed in SEQ ID NO 4, 5, and 6. SEQ ID NO 9 encodes the polypeptide of SEQ ID NO 10. The specification discloses that the cDNA synthesized from porcine retroviral RNA were cloned in a plasmid vector and the sequences of the clones were determined. The specification also teaches that the earlier

identified sequence is disclosed in figure 1, followed by the sequence of figure 2 and finally sequence 3 was obtained (see first paragraph on page 4). The polynucleotide sequences disclosed in the figures 1, 2, and 3 represent the sequence of the polynucleotides disclosed in SEQ ID NO 1, 2, and 3 respectively.

The specification further teaches that the polynucleotide sequence of SEQ ID NO 3 has three open reading frames, of 524, 1194, and 656 amino acids each which by sequence homology are the Gag, Pol and Env proteins of the porcine retrovirus. However, from the disclosure of the specification it is unclear whether the sequences disclosed in SEQ ID NO 1 is a smaller fragment of the polynucleotide disclosed in SEQ ID NO 3 or 2 whether it is an independent sequence. It is noted that the polynucleotides of SEQ ID NO 2 and 3 differ in size by only 13 nucleotides whereas the polynucleotide of SEQ ID NO 1 has only 3320 nucleotides. On page 22, the specification discloses that the polynucleotides of SEQ ID NO 1 has 100% sequence similarity between 21-2681 and 2972-5653 and over it has 70.5% sequence identity with SEQ ID NO 3. The specification does not teach whether the polypeptides encoded by SEQ ID NO 1 and by 2 and 3 are same and/or how related they are. Furthermore, whether the polypeptides encoded by SEQ ID NO 1 ORF, 924 and 218 amino acids in length would have the activity of Pol and Env proteins encoded by SEQ ID NO 2 and 3. In the absence of any disclosure about the function of these polynucleotides it is not clear whether any of the fragments of SEQ ID NO 1 will encode any protein, which would have the physiological activity of the Pol, and Env protein. Furthermore, regarding the immunogenic activity, the specification does not teach which parts of the proteins Gag, Pol, and Env are immunogenic and therefore, it is not clear which fragments of SEQ ID NO 1, 2 or 3 would encode for proteins that would have immunogenic activity.

Regarding the polynucleotides that have at least 90% or 25% sequence identity with SEQ ID NO 1, 2, 3, or 9, the issue is: will any polynucleotide in which 10% or 25% of the nucleotide sequences disclosed in SEQ ID NO 1, 2, 3 or 9 have been changed, encode a protein that would have the functions of Gag, Pol, and Env of porcine virus? Since the sequence encodes three different polynucleotides, based on which part of the sequence of SEQ ID NO 2 or 3 is altered, the encoded protein

may not even be a Gag, Pol, or Env, for example, due to frame shift. Furthermore, claimed polynucleotides would encompass variants that encode mutant proteins due to deletion, substitution, and addition in the wild type polynucleotides. It is recognized in the prior art that the function of a protein depends on the sequence of its amino acids in a certain pattern, conformation of the protein due to the amino acid sequence, and the functional properties of the different parts of the protein (see second paragraph in Rudinger J in Peptide Hormones. Editor Parsons JA. Pages 1-7, 1976, University Park Press, Baltimore). Rudinger further add, "The significance of particular amino acids and sequences for different aspects of biological activity can not be predicted *a priori* but must be determined from case to case by painstaking experimental study" (see conclusion on page 6). The specification does not teach which changes in the nucleotide sequence of SEQ ID NO 2 or 3 would encode amino acid sequences that would retain the function of the encoded proteins. The specification does not teach how to use a nucleic acid that would have encoded proteins that did not have the function of the wild type protein. It is noted that if the specification was not enabling for the polynucleotides, an artisan would not know how to use the vector comprising the polynucleotide or the host cell comprising the vector.

Accordingly, the specification is not enabling for the claimed invention because the specification does not provide sufficient guidance, working examples, and evidence as to how an artisan would have made and used the claimed invention without undue experimentation and therefore, limiting the scope of the claimed invention to (i) an isolated polynucleotide disclosed in SEQ ID NO 1, 2 and 3 wherein the polynucleotides of SEQ ID NO 2 and 3 have three open reading frames (ORFs) of 524 (SEQ ID NO 4), 1194 (SEQ ID NO 5), and 656 amino acids each (SEQ ID NO 6) (ii) an isolated polynucleotide disclosed in SEQ ID NO 9 which encodes the protein disclosed in SEQ ID NO 10, vector comprising the polynucleotides of (i) and (ii), and an isolated recombinant host cell comprising the polynucleotides of (i) and (ii), is proper.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 57, 58, and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 57 is indefinite because it is dependent on claim 56 which recites oligonucleotides of at least 30 nucleotides, however, the oligonucleotides recited in SEQ ID NO 13 is only 20 nucleotides.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. Claims 43-47 and 49-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Fishman (US 6190861, 2-20-2001, filing date 12-14-1995).

Fishman teaches swine retroviruses and methods of using such. The sequences of SEQ ID NO 1 of the instant application has more than 86% sequence identity over the sequence of SEQ ID NO 3 of Fishman et al whereas SEQ ID NO 3 of the instant application has more than 76% sequence identity over the sequence of SEQ ID NO 3 of Fishman et al. The sequence of SEQ ID NO 9 of the instant application has more than 97% sequence identity over the sequence of SEQ ID NO 3 of Fishman. The sequence of SEQ ID NO 13 and 14 of the instant application also have 100% sequence identity to parts of SEQ ID NO 3 of Fishman. Fishman et al also teaches method of detection and other methods (see columns 1-38 of Fishman. Accordingly, the invention of claims 43-47 and 49-64 is anticipated by Fishman.

11. No claim is allowed.

When amending claims, applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c). For instructions, Applicants are referred to http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm.

Applicants are also requested to submit a copy of all the pending/under consideration claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (703) 305-3388.

Ram R. Shukla, Ph.D.

Ram R. Shukla

RAM R. SHUKLA, PH.D
PATENT EXAMINER